

Notice of Allowability

Application No.

09/575,580

Examiner

Chih-Min Kam

Applicant(s)

MCKEON ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/26/07.
2. ☒ The allowed claim(s) is/are 9,10,17-19,21-23 and 25-29.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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DETAILED ACTION

Status of the Claims

1. Claims 9-10, 17-19, 21-23 and 25-29 are pending.

Applicants' amendment filed June 26, 2007 is acknowledged. Applicants' response has been fully considered. Claims 9, 17, 18, 21 and 25-27 have been amended, and claims 8, 20 and 24 have been cancelled. Therefore, claims 9-10, 17-19, 21-23 and 25-29 are examined.

Withdrawn Claim Objections

2. The previous objection to claims 19, 23 and 29 is withdrawn in view of applicants' amendment to the claims in the amendment filed June 26, 2007.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 8-10, 17, 18, 20-22 and 24-28 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at page 4 in the amendment filed June 26, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Isabelle M. Clauss on September 11, 2007.

Examiner's Amendment to the Specification:

Please replace the term "Figure 24" at page 11, line 18 with the term "Figures 24A and 24B".

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Please replace the term "Figure 25" at page 11, line 21 with the term "Figures 25A and 25B".

Please replace the term "Figure 26" at page 11, line 24 with the term "Figures 26A and 26B".

Examiner's Amendment to the Claims:

Claims 17, 18, 21, 22, 27 and 28 have been amended as follows:

17. (Currently amended) A method for identifying a compound that modulates the activity or level of a calcipressin (Csp) protein, comprising contacting a cell comprising a Csp protein with a test compound and determining the level or activity of the Csp protein in the cell, wherein a higher or lower level or activity of the Csp protein in the cell contacted with the test compound relative to a cell that was not contacted with the test compound indicates that the test compound is a compound that modulates the activity or level of the Csp protein, wherein said activity of the Csp protein is the binding activity of the Csp protein to calcineurin or ~~inhibition~~ the inhibitory activity of the Csp protein toward calcineurin, and wherein the Csp protein comprises an amino acid sequence that ~~is~~ has at least 95% or about 95% identical sequence identity to amino acids 50-197 of SEQ ID NO: 4.

18. (Currently Amended) The method of claim 17, wherein the Csp protein comprises an amino acid sequence that ~~is~~ has at least 99% or about 99% identical sequence identity to amino acids 50-197 of SEQ ID NO: 4.

21. (Currently amended) A method for identifying a compound that modulates the activity or level of a calcipressin (Csp) protein, comprising contacting a cell comprising a Csp protein with a test compound and determining the level or activity of the Csp protein in the cell, wherein a higher or lower level or activity of the Csp protein in the cell contacted with the test compound relative to a cell that was not contacted with the test compound indicates that the test compound is a compound that modulates the activity or level of the Csp protein, wherein said activity of the Csp protein is the binding activity of the Csp protein to calcineurin or ~~inhibition~~ the inhibitory activity of the Csp protein toward calcineurin, and wherein the Csp protein

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comprises an amino acid sequence that is has at least 95% or about 95% identical sequence identity to SEQ ID NO: 4.

22. (Currently amended) The method of claim 21, wherein the Csp protein comprises an amino acid sequence that is has at least 99% or about 99% identical sequence identity to SEQ ID NO: 4.

27. (Currently Amended) A method for identifying a compound that modulates the activity or level of a calcipressin (Csp) protein, comprising contacting a cell comprising a Csp protein with a test compound and determining the level or activity of the Csp protein in the cell, wherein a higher or lower level or activity of the Csp protein in the cell contacted with the test compound relative to a cell that was not contacted with the test compound indicates that the test compound is a compound that modulates the activity or level of the Csp protein, wherein said activity of the Csp protein is the binding activity of the Csp protein to calcineurin or ~~inhibition~~ the inhibitory activity of the Csp protein toward calcineurin, and wherein the Csp protein comprises an amino acid sequence that is has at least 95% or about 95% identical sequence identity to SEQ ID NO: 5.

28. (Currently Amended) The method of claim 27, wherein the Csp protein comprises an amino acid sequence that is has at least 99% or about 99% identical sequence identity to SEQ ID NO: 5.

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be related to the claimed invention. Fuentes *et al.* (Human Molecular genetics 4, 1935-1944 (1995) teach a new human gene from Dow syndrome critical region encodes a proline-rich protein (DSCR1), which is highly expressed in fetal brain and heart and has about 95% sequence identity to Csp1 (SEQ ID NO:4). However, the reference does not teach a method for identifying a compound that modulates the activity or level of the DSCR1 protein by contacting a cell containing the protein with a test compound and determining the level or activity of the protein. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

September 11, 2007